IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

CORCEPT THERAPEUTICS, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 18-03632 (RMB) (LDW) (consolidated) **OPINION**

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RENÉE MARIE BUMB, Chief United States District Judge:

This is a "Hatch-Waxman Act" case for patent infringement brought by Plaintiff Corcept Therapeutics, Inc. ("**Corcept**") against Defendant Teva Pharmaceuticals USA, Inc. ("**Teva**") pursuant to 35 U.S.C. § 271(b) and 271(e)(2)(A). Teva seeks to market and sell a generic version of Corcept's 300 mg branded drug, Korlym® (mifepristone), prior to the expiration of certain Corcept patents. Following Teva's submission of Abbreviated New Drug Application No. 211436 to the United States Food and Drug Administration for commercial approval of its generic drug product, Corcept initiated this suit seeking, *inter alia*, a declaration of patent infringement and a permanent injunction restraining Teva from launching its generic mifepristone product prior to the expiration of the Patents-in-Suit (defined below).

On February 27, 2023, the Court denied the parties' cross-motions for summary judgment, observing that it was critical to hear "expert testimony regarding [Teva's] label's dosing regimens available when healthcare providers co-administer mifepristone with strong CYP3A inhibitors." [Docket No. 229.] This action proceeded to a three-day bench trial on September 26, 2023. [Transcript of Bench Trial, Docket Nos. 284, 285, 286 ("**Tr.**").] The sole issue presented to the Court was whether Teva induced infringement of claims 10–13 of United States Patent No. 10,195,214 ("**the '214 Patent**") and claims 1, 6, 7, and 9 of United States Patent No. 10,842,800 ("**the '800 Patent**") (the "**Patents-in-Suit**"). [*See generally* Def.'s Pretrial Br., Docket No. 269; Pl.'s Pretrial Br., Docket No. 270.] Claim 10 of the '214 Patent

and claims 1 and 6 of the '800 Patent are the only independent claims asserted. The Court heard evidence, including live testimony from the parties' respective expert witnesses,[1] and thereafter directed the submission of post-trial briefing.[2]

Having considered the parties' briefs, the evidence of record, and the applicable law, the Court concludes that Corcept has not met its burden of proof: it has not demonstrated that there is a likelihood of direct infringement of the asserted claims in the future because it has not established that physicians are likely to coadminister mifepristone with a strong CYP3A inhibitor at an infringing sequence and/or dosage now or in the future. Indeed, Corcept failed to introduce credible record evidence that anyone has ever previously infringed the asserted claims. *See Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1380 (Fed. Cir. 2022). Additionally, Corcept failed to demonstrate that Teva possesses the specific intent to encourage physicians to infringe the asserted claims because Teva's proposed product label does not clearly "encourage, recommend, or promote" infringement. *See Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). Accordingly, the Court will enter

[1] The Court heard live testimony from Dr. Joseph Belanoff (co-founder, CEO, and President of Corcept, and the inventor associated with the Patents-in-Suit); Dr. Ty Carroll (Corcept's expert witness); and Dr. Peter Snyder (Teva's expert witness). The Court also heard deposition testimony via video from Dr. Adrian Dobs, Mr. Gregg DeRosa, Mr. Craig Jones, Mr. Sean Maduck, and Dr. Andreas Moraitis.

[2] The parties submitted their briefs accordingly. [Def.'s Post-Trial Br., Docket No. 288; Pl.'s Post-Trial Br., Docket No. 289; Def.'s Post-Trial Reply Br., Docket No. 294; Pl.'s Post-Trial Reply Br., Docket No. 295.]

judgment in Teva's favor. This Opinion constitutes the Court's findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

I. BACKGROUND

A. The Parties, Standing, and Jurisdiction.

Corcept is a publicly traded corporation organized under the laws of the State of Delaware, with a principal place of business in Menlo Park, California. [Final Pre-Trial Order ("**FPTO**"), Tab 2, Stipulated Facts ¶ 2, Docket No. 273.] Teva is a corporation organized under the laws of the State of Delaware, with a principal place of business in Parsippany, New Jersey. [*Id.* ¶ 1.] (Teva's global headquarters is located in Tel Aviv, Israel.)

As the assignee of the Patents-in-Suit, [Tr. at 127:4–10 (Dr. Belanoff) (citing PTX-001, PTX-003)], Corcept has standing to maintain this litigation. *See Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998) ("[A]n assignee is the patentee and has standing to bring suit for infringement in its own name.") (citing 35 U.S.C. § 100(d)).

Because this action arises under the patent laws of the United States, this Court exercises subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

B. The Hatch-Waxman Act.

Under the Federal Food, Drug, and Cosmetic Act ("**FDCA**"), 21 U.S.C. § 301, *et seq.*, the United States Food and Drug Administration ("**FDA**") must approve a new

drug prior to its introduction on the market. 21 U.S.C. § 355(a). To secure the FDA's approval, a drug applicant may file a New Drug Application ("**NDA**") that includes certain specified information, including examples of the proposed label for the drug and any patents that claim the drug, or a method of using the drug, if an infringement claim could reasonably be asserted. *Id.* § 355(b)(1)(A)(vi), (viii). "The FDA publishes the names of approved drugs and their associated patent information in the *Approved Drug Products with Therapeutics Equivalence Evaluations* list, commonly referred to as the 'Orange Book.' " *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1045 (Fed. Cir. 2010).

Where a drug applicant seeks the FDA's approval to introduce a generic version of an approved drug, the drug applicant may file an Abbreviated New Drug Application ("**ANDA**"). 21 U.S.C. § 355(j). An ANDA is a more streamlined submission than an NDA, allowing the applicant to rely on the safety and efficacy information of a drug listed in the Orange Book if the applicant can demonstrate "bioequivalence." *See AstraZeneca*, 633 F.3d at 1045; *see also* 21 U.S.C. § 355(j)(2)(A). Congress permitted the submission of ANDAs, rather than full NDAs, under the Hatch-Waxman Act,[3] as part of a deliberate and carefully constructed scheme to balance competing policy priorities in the pharmaceuticals industry. On the one hand,

[3] The "Hatch-Waxman Act" is the more common referent for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(c), 35 U.S.C. §§ 156, 271, 282), as amended by the Medicare Prescription Drug Improvement and Modernization act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Sometimes the law is referred to as the "Hatch Waxman Amendments" to the FDCA. *See, e.g.*, *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–71 (Fed. Cir. 2002).

Congress sought to encourage "pioneering research and development of new drugs," while on the other hand, "enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (explaining that Congress authorized ANDAs, substantially shortening the time and effort needed to obtain marketing approval, to eliminate the *de facto* extension of a patent's term, and to enable new drugs to be marketed more quickly and cheaply).

Under a safe harbor provision, it is not an act of patent infringement to research, develop, test, and collect information for submission of a drug application to the FDA. *See* 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under [applicable law]."); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). Under § 271(e)(2)(A), however, it *is* an act of patent infringement for a generic drug applicant to file an ANDA seeking approval of a generic drug product claimed by a valid and unexpired patent. *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Andrx Pharms.*, 276 F.3d at 1371. This provision, based on a somewhat "artificial" act of infringement, has been considered a "jurisdictional-conferring statute" invoked to establish a case or controversy in a declaratory judgment action. *Glaxo Grp.*, 376 F.3d at 1351 (citing *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322,

1330 (Fed. Cir. 2003)); *see also Eli Lilly & Co.*, 496 U.S. at 676 (explaining that § 271(e)(2) is based on a "somewhat artificial[] act of infringement for a very limited and technical purpose").

As part of the approval process, an ANDA applicant must file one of four certifications concerning every patent that claims the listed drug that is the subject of the application, or a method of using the drug: (I) "that such patent information has not been filed," (II) "that such patent has expired," (III) "the date on which such patent will expire," or (IV) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV). An applicant who files a "Paragraph IV" certification must give notice to the holder of the patents at issue that an ANDA has been filed, and the applicant must state the basis for its belief that the patents are not valid or will not be infringed. *Id.* § 355(j)(2)(B)(i), (ii). The ANDA becomes effective 45 days thereafter unless the patentee commences suit. *Id.* § 355(c)(3)(C). Subject to certain exceptions, if a patent infringement suit is commenced, then the ANDA will not become effective until the expiration of an automatic 30-month stay. *Id.*; *see also Eli Lilly & Co.*, 496 U.S. at 677–78 (explaining certification process).

C. Cushing's Syndrome and Treatment.

Relevant to the dispute before the Court is the rare and debilitating endocrine disorder, Cushing's syndrome. Endogenous Cushing's syndrome is characterized by excessive production of the adrenal hormone cortisol. [Tr. at 120:15–16 (Dr. Belanoff); Tr. at 382:1–3 (Dr. Snyder); *see also* Tr. at 52:18–53:2 (Dr. Dobs)

(differentiating endogenous and exogenous Cushing's syndrome, the latter signifying a cause outside of the body).] Endogenous Cushing's syndrome often results from the presence of a tumor in the adrenal or pituitary glands that stimulates, either directly or indirectly, the overproduction of cortisol. [Tr. at 120:16–19 (Dr. Belanoff); Tr. at 382:3–8 (Dr. Snyder).] As Dr. Snyder put it, excess cortisol is "really bad." [Tr. at 382:12.] It can lead to hyperglycemia (*i.e.*, high blood sugar), hypertension, obesity, osteoporosis, depression, sexual dysfunction, menstrual disorders, and infertility, among other problems and complications. [Tr. at 382:11–17 (Dr. Snyder); *see also, e.g.*, Rosario Pivonello *et al.*, *The Treatment of Cushing's Disease*, Endocrine Rev., Aug. 2015, at 385, 386 (describing manifestations of Cushing's syndrome) (PTX-015.01).]

The first-line treatment for a patient suffering from Cushing's syndrome is surgery. [Tr. at 53:15–54:11 (Dr. Dobs); Tr. at 120:22–25 (Dr. Belanoff); Tr. at 382:21–24 (Dr. Snyder).] Excising the "offending tumor" is preferred for multiple reasons, not least of which is that it is the most efficient option from a medical and financial "point of view." [Tr. at 53:21–54:1 (Dr. Dobs); *see also* Tr. at 382:23–24 (Dr. Snyder).] A majority of those who suffer from hypercortisolism undergo surgery and are cured. [Tr. at 236:12–18 (Dr. Carroll); *see* Tr. at 120:24–121:4 (Dr. Belanoff) (explaining that surgery is only possible "about half the time").] However, if surgical intervention is not an option for the patient or surgery has already yielded an unsuccessful result, physicians will consider medical therapies (*i.e.*, medication). [Tr. at 382:25–383:3 (Dr. Snyder); Tr. at 54:22–55:3 (Dr. Dobs); *see also, e.g.*, Pivonello *et*

al., *supra*, at 396 (Fig. 2) (depicting schematic algorithm for treating Cushing's disease, prioritizing surgery followed by medical therapy) (PTX-015.12).]

Today, there are a few medications available to treat Cushing's syndrome when surgery is not an option. [*See* Tr. at 55:24–56:2 (Dr. Dobs).] One group of medications that is often prescribed—called "CYP3A inhibitors"—impedes the synthesis of cortisol in the adrenal glands, thereby "blocking" excessive cortisol at its source. This group includes ketoconazole and metyrapone, among others. [Tr. at 383:6–12 (Dr. Snyder).] CYP3A inhibitors are a broad therapeutic class of drugs that target multiple different diseases, often addressing specific manifestations of Cushing's syndrome. [*See* Tr. at 129:6–131:6 (Dr. Belanoff) (explaining that CYP3A inhibitors, such as ketoconazole, itraconazole, nefazodone, ritonavir, nelfmavir, and clarithromycin, are often the "best choice" for addressing a particular manifestation of Cushing's syndrome).] However, these medications also suppress the activity of CYP3A enzymes, which are the enzymes that metabolize most drugs. [*See* Tr. at 127:19–24 (Dr. Belanoff).] As a result, there is the potential for adverse drug-drug interactions. [*See* Tr. at 127–28 (Dr. Belanoff); *see also generally* Lynette K. Nieman, *Medical Therapy of Hypercortisolism (Cushing's Syndrome)*, UpToDate (last updated Aug. 29, 2022) [DTX-034]).]

Another medication is mifepristone, which "antagonizes the effects of cortisol," [Tr. at 121:5–6 (Dr. Belanoff)], by blocking cortisol from binding to a glucocorticoid receptor, [Tr. at 383:9–12 (Dr. Snyder); *see generally* Pivonello *et al.*, *supra*, at 455–58 (PTX-015.71–74)]. Unlike a CYP3A inhibitor that prevents production of cortisol, mifepristone manages cortisol's effects. [*See, e.g.*, Tr. at 121:5–6 (Dr. Belanoff).] The

major benefit of mifepristone is that it acts quickly and can be used to stabilize a very sick patient, while that patient waits for surgery, for instance. [Tr. at 385:6–13 (Dr. Snyder); Tr. at 57:15–58–12 (Dr. Dobs).] The major drawback, however, is inherent in mifepristone's function: by blocking cortisol's "action," mifepristone does not actually inhibit cortisol production. Cortisol levels can thus increase even though mifepristone is being used. This can lead to dosing problems because a prescribing physician cannot use cortisol levels to determine the right dose. [*See* Tr. at 385–86 (Dr. Snyder).]

Mifepristone is rarely, if ever, prescribed in combination with a strong CYP3A inhibitor, such as ketoconazole, to treat Cushing's syndrome. [*See, e.g.*, Tr. at 58:19–25 (Dr. Dobs) (explaining generally that she has prescribed mifepristone with ketoconazole only "about two to three times" where a patient was "extremely ill"); Tr. at 410:9–22 (Dr. Snyder) (noting that he has never co-administered mifepristone with a strong CYP3A inhibitor and "can't think of any situation where it would be necessary," where the benefits would outweigh the risk).] As will be discussed herein, co-administration can be risky because it can increase mifepristone levels in the blood and cause resulting health consequences, as strong CYP3A inhibitors block CYP3A enzymes from metabolizing mifepristone. [Tr. at 212:1–7 (Dr. Carroll); Tr. at 127–28, 131 (Dr. Belanoff).]

In this regard, Dr. Snyder testified that a newer drug, osilodrostat, is now being used to treat Cushing's syndrome. [Tr. at 384, 386, 393 (Dr. Snyder).] It is a powerful drug that acts quickly by inhibiting the synthesis of cortisol. [Tr. at 386 (Dr. Snyder).]

While osilodrostat's branded version (Isturisa®) is only indicated for the treatment of Cushing's disease, Dr. Snyder testified that it is now widely used off-label for the treatment of Cushing's syndrome. [Tr. at 474, 476 (Dr. Snyder).] Its principal advantage in this context is that physicians can rely on cortisol levels to determine the proper dose. [Tr. at 384, 386 (Dr. Snyder).]

D. Korlym® and Discovery of the Claimed Invention.

In the years after Corcept was founded (in 1998), Dr. Belanoff and the company focused on developing a treatment for psychotic depression. [Tr. at 117–120 (Dr. Belanoff).] Because of cortisol's systemic bodily effect, Dr. Belanoff was particularly interested in, and focused Corcept's research and development activities on, cortisol modulation. [Tr. at 120 (Dr. Belanoff).] Corcept became aware that researchers had reported the successful treatment of Cushing's syndrome with mifepristone—a drug that had been around since 1985—but that there was not an FDA-approved medication on the market. [Tr. at 120–21, 123, 157 (Dr. Belanoff).] In 2007, Corcept filed an Investigational New Drug Application to evaluate a mifepristone product for the treatment of Cushing's syndrome, and it soon designed a clinical study that produced "potent and positive" results. [Tr. at 122 (Dr. Belanoff).] Corcept named its efficacy study "SEISMIC." [Tr. at 121–22 (Dr. Belanoff).] These results supported Corcept's NDA No. 202107 for approval of its product. [Tr. at 122 (Dr. Belanoff).]

In 2012, the FDA approved Corcept's mifepristone product, Korlym®, for the following indication: "for the control of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes

mellitus or glucose intolerance and have failed surgery or are not candidates for surgery." [FPTO, Tab 2, Stipulated Facts ¶¶ 31, 33; *see* Tr. at 123:9–12 (Dr. Belanoff); JTX-015.] When the drug was approved, it qualified for orphan status, with an estimated market of 5,000 patients. [Tr. at 123:15–18 (Dr. Belanoff).] More than ten years on, Korlym® is today prescribed to about 1,500 patients. [Tr. at 123:17–18 (Dr. Belanoff).]

In connection with the product's initial approval, the FDA required Corcept to conduct drug-drug interaction studies to determine the effect of coadministration of mifepristone with a strong CYP3A inhibitor. [Tr. at 136–37 (Dr. Belanoff).] The FDA's directive is reflected as a post-marketing requirement in its initial approval letter. [PTX-012.3 (approval letter).] The FDA required post-marketing studies to be conducted because it recognized that ketoconazole (an exemplary CYP3A inhibitor) was widely used off-label to treat Cushing's syndrome and that increased exposure to mifepristone might result from coadministration, potentially leading to severe hypokalemia and adrenal insufficiency. [Tr. at 136–39 (Dr. Belanoff); *see* PTX-012.3–4.] Dr. Belanoff agreed with the FDA's directive to conduct "rigorous" and "robust" studies to quantify the effects of coadministration on mifepristone blood levels, as he was fearful that concomitant use could lead to severe effects, including death. [Tr. at 131:20–25, 137:13–139:4.] He also testified that there was an awareness at the time of approval that physicians were already administering mifepristone with a strong CYP3A inhibitor in very sick patients in isolated cases. [Tr. at 132:6–11, 138:14–20; PTX-012.4.] According to Dr. Belanoff and Dr. Carroll, doctors desired to

coadminister the drugs but avoided doing so, unless medically necessary, due to safety concerns. [Tr. at 143:13–144:12, 146:8–22 (Dr. Belanoff); Tr. at 211:8–11, 211:21–212:7 (Dr. Carroll).]

Corcept's initial 2012 Korylm® label was approved with the following warnings regarding coadministration of mifepristone and strong CYP3A inhibitors:

- **Warnings & Precautions** – *Use of Strong CYP3A Inhibitors:* Concomitant use can increase mifepristone plasma levels significantly. Use only when necessary and limit mifepristone dose to 300 mg (5.6). [JTX-015.1.]
- **Drug Interactions** – CYP3A inhibitors: Caution should be used when Korlym is used with strong CYP3A inhibitors. Limit mifepristone dose to 300 mg per day when used with strong CYP3A inhibitors. (5.6, 7.2). [JTX-015.1.]
- **5.6 Use of Strong CYP3A Inhibitors** – Korlym should be used with extreme caution in patients taking ketoconazole and other strong inhibitors of CYP3A, such as itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, atazanavir, amprenavir, fosamprenavir, boceprevir, clarithromycin, conivaptan, lopinavir, nefazodone, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, or voriconazole, as these could substantially increase the concentration of mifepristone in the blood. The benefit of concomitant use of these agents should be carefully weighed against the potential risks. Mifepristone should be used in combination with strong CYP3A inhibitors only when necessary, and in such cases the dose should be limited to 300 mg per day. [*See Warnings & Precautions (5.4), Drug Interactions (7.2), and Clinical Pharmacology (12.3).*] [JTX-015.6.]
- **7.2 CYP3A Inhibitors** – Medications that inhibit CYP3A could increase plasma mifepristone concentrations and dose reduction of Korlym may be required. [¶] Ketoconazole and other strong inhibitors of CYP3A, such as itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, atazanavir, amprenavir and fosamprenavir, boceprevir, clarithromycin, conivaptan, lopinavir, mibefradil, nefazodone, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, or voriconazole may increase exposure to mifepristone significantly. The clinical impact of this interaction has not been studied. Therefore, extreme caution should be used when these drugs are prescribed in

> combination with Korlym. The benefit of concomitant use of these agents should be carefully weighed against the potential risks. The dose of Korlym should be limited to 300 mg and used only when necessary. [*See Warnings & Precautions (5.6)*]. [JTX-015.9–10.]

[JTX-015 (Corcept's 2012 Korlym® Label).] Dr. Belanoff testified that the 2012 label represented a "forceful[]" warning to physicians not to coadminister mifepristone with strong CYP3A inhibitors. [*See* Tr. at 145–48, 149–50 (Dr. Belanoff) (citing prior declaration to Patent Office, characterizing 2012 product label as "forcefully" warning that coadministration might be dangerous).]

In the years that followed, as required, Corcept conducted a series of clinical trials under a variety of conditions, hypothesizing that mifepristone blood levels would "skyrocket" if mifepristone and a strong CYP3A inhibitor were taken together. [Tr. at 128, 131 (Dr. Belanoff).] Rather, Corcept discovered that mifepristone blood levels only increased marginally and that a physician could prescribe up to 900 mg of mifepristone with a strong CYP3A inhibitor if dosed appropriately. [Tr. at 128–31, 151–55 (Dr. Belanoff).] Based on this discovery, Corcept filed a patent application in March 2017 that led to the issuance of the '214 Patent and '800 Patent. Corcept also asked the FDA to approve modifications to its original product label. [Tr. at 151 (Dr. Belanoff).] The current label, revised in November 2019, includes the following language regarding coadministration (with modifications noted in-line):

- **Warnings and Precautions** – *Use of Strong CYP3A Inhibitors:* Concomitant use can increase mifepristone plasma levels [~~significantly~~]. Use only when necessary and limit mifepristone dose to ***900 mg*** (5.6). [JTX-016.1 (Corcept's 2019 Korlym® Label) (strikethrough and emphasis added).]

- **Drug Interactions** – CYP3A inhibitors: Caution should be used when KORLYM is used with strong CYP3A inhibitors. Limit mifepristone dose to ***900 mg*** per day when used with strong CYP3A inhibitors (7.2). [JTX-016.1 (emphasis added).]
- **2.5 Concomitant Administration with CYP3A Inhibitors** – Ketoconazole and other strong inhibitors of CYP3A, such as itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, atazanavir, amprenavir and fosamprenavir, clarithromycin, conivaptan, lopinavir/ritonavir, posaconazole, saquinavir, telithromycin, or voriconazole may increase exposure to mifepristone. KORLYM should be used in combination with strong CYP3A inhibitors only when necessary. [*See Warnings and Precautions (5.6), Drug Interactions (7.2)*].

  Administration of KORLYM to patients already being treated with strong CYP3A inhibitors:
  - Start at a dose of 300 mg. If clinically indicated, titrate to a maximum of 900 mg.

  Administration of strong CYP3A inhibitors to patients already being treated with KORLYM:
  - Adjust the dose of KORLYM according to Table 1.

Table 1. Dose adjustment of KORLYM when strong CYP3A inhibitor is added

Current dose of KORLYM	Adjustment to dose of KORLYM if adding a strong CYP3A inhibitor
300 mg	No change
600 mg	Reduce dose to 300 mg. If clinically indicated, titrate to a maximum of 600 mg
900 mg	Reduce dose to 600 mg. If clinically indicated, titrate to a maximum of 900 mg
1200 mg	Reduce dose to 900 mg

[JTX-016.4 (new instruction regarding coadministration).]

- **5.6 Use of Strong CYP3A Inhibitors** – KORLYM should be used with [~~extreme~~] caution in patients taking ketoconazole and other strong inhibitors of CYP3A, such as itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, atazanavir, amprenavir, fosamprenavir, clarithromycin, conivaptan, lopinavir/ritonavir, posaconazole, saquinavir, telithromycin, or voriconazole, as these could [~~substantially~~] increase the concentration of mifepristone in the blood. The benefit of concomitant use of these agents should be

carefully weighed against the potential risks. KORLYM should be used in combination with strong CYP3A inhibitors only when necessary, and in such cases the dose should be limited to ***900 mg*** per day. [*See Warnings & Precautions (5.4), Drug Interactions (7.2), and Clinical Pharmacology (12.3)*]. [JTX-016.6 (strikethroughs and emphasis added).]

- **7.2 CYP3A Inhibitors** – Ketoconazole and other strong inhibitors of CYP3A, such as itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, atazanavir, amprenavir and fosamprenavir, clarithromycin, conivaptan, lopinavir/ritonavir, posaconazole, saquinavir, telithromycin, or voriconazole may increase exposure to mifepristone [~~significantly~~]. [~~The clinical impact of this interaction has not been studied~~.] [~~Therefore, extreme~~] Caution should be used when strong CYP3A inhibitors are prescribed in combination with KORLYM. The benefit of concomitant use of these agents should be carefully weighed against the potential risks. The dose of KORLYM should be limited to ***900 mg***, and strong inhibitors of CYP3A should be used only when necessary. [*See Dosage and Administration (2.4), Warnings & Precautions (5.6), and Clinical Pharmacology (12.3)*]. [JTX-016.11 (strikethroughs and emphasis added).]

[JTX-016 (Corcept's 2019 Korlym® Label); *see also* Tr. at 151–55 (Dr. Belanoff) (describing changes to label).] The Clinical Pharmacology section of the 2019 Korlym® label (Section 12.3) now includes data from Corcept's clinical trials reflecting the drug-drug interaction effects of coadministering mifepristone with a strong CYP3A inhibitor. [JTX-016.16–17.] Specifically, Table 3 lists the average ratios of blood concentrations of mifepristone with and without coadministration of a variety of drugs. [Tr. at 403–04 (Dr. Snyder) (summarizing purpose of, and information contained in, table).] Table 3 is reproduced in full below:

Table 3. Summary Table of KORLYM Drug-Drug Interaction Effects

Dosing of Mifepristone	Coadministered Drug	Dosing of Coadministered Drug	Geometric Mean Ratio (analyte ratio with/without drug coadministration)		
			Analyte	AUC	Cmax
Effect of KORLYM on Coadministered Drug					
Contraindicated with mifepristone *[See Contraindications (4)]*					
1200 mg once daily for 10 days	simvastatin[1]	80 mg single dose	simvastatin acid simvastatin	15.70 10.40	18.20 7.02
Use lowest dose of coadministered drug, based on clinical experience and/or use of therapeutic drug monitoring					
1200 mg once daily for 10 days	alprazolam[2]	1 mg single dose	alprazolam 4-hydroxy-alprazolam	1.80 0.76	0.81 0.39
1200 mg once daily for 7 days	fluvastatin[3]	40 mg single dose	fluvastatin	3.57	1.76
1200 mg once daily for 10 days	digoxin[4]	0.125 mg once daily	digoxin	1.40	1.64
Effect of Coadministered Drug on KORLYM					
Dose adjustment required					
600 mg once daily for 17 days	ketoconazole	200 mg bid on days 13-17	mifepristone Metabolite 1† Metabolite 2† Metabolite 3†	1.38 1.02 1.67 0.95	1.28 1.06 1.69 0.96
900 mg once daily for 14 days	itraconazole	200 mg daily for 14 days	mifepristone Metabolite 1† Metabolite 2† Metabolite 3†	1.10 1.04 1.23 0.97	1.20 1.00 1.19 0.94
Effect of Coadministered Drug on KORLYM					
No dosing adjustment required					
300 mg once daily for 14 days	cimetidine[5]	800 mg once daily	mifepristone	0.85*	0.75

*No effect = 90% CI within range 0.80 – 1.25

†See Section 12.2 for the relative potencies of the three metabolites

[1] Simvastatin 40 mg dose used as reference for the comparison. Result could be representative of other oral drugs with CYP3A metabolism and high first pass effect: cyclosporine, midazolam, triazolam, pimozide, sildenafil, sirolimus, and tacrolimus

[2] Result could be representative of other oral drugs with CYP3A metabolism and low first pass effect. Clinical significance of any interaction will depend on the therapeutic margin of the drug.

[3] Result could be representative of other oral drugs with CYP2C8/C9 metabolism

[4] Plasma digoxin concentration should be measured after 1 to 2 weeks of concomitant use and following usual clinical practice at appropriate intervals thereafter.

[5] Result could be representative of other mild inhibitors of CYP3A

[JTX-016.16–17.]

E. The Patents-in-Suit.

There are two remaining patents in this litigation: the '214 Patent and the '800 Patent. Both involve methods of controlling hyperglycemia in certain patients who have Cushing's syndrome. [*See generally* JTX.001 ('214 Patent); JTX.003 ('800 Patent).] The claims embodied in these patents are based on Corcept's findings following the post-marketing studies that the FDA required, as summarized above.

The only asserted independent claim of the '214 Patent is claim 10, which involves coadministering 600 mg of mifepristone with a strong CYP3A inhibitor, after titrating down from 1200 mg or 900 mg of mifepristone:

> **10**. A method of controlling hyperglycemia secondary to hypercortisolism in a patient with endogenous Cushing's syndrome who is taking an original once-daily dose of 1200 mg or 900 mg per day of mifepristone, comprising the steps of:
>
> reducing the original once-daily dose to an adjusted once-daily dose of 600 mg mifepristone,
>
> administering the adjusted once-daily dose of 600 mg mifepristone and a strong CYP3A inhibitor to the patient,
>
> wherein said strong CYP3A inhibitor is selected from the group consisting of ketoconazole, itraconazole, nefazodone, ritonavir, nelfmavir, indinavir, boceprevir, clarithromycin, conivaptan, lopinavir, posaconazole, saquinavir, telaprevir, cobicistat, troleandomycin, tipranivir, paritaprevir and voriconazole.

[JTX-001.37 ('214 Patent, 68:47–63) (Claim 10).] Claim 1 of the '800 Patent is nearly identical to claim 10 of the '214 Patent, except that it requires concomitant administration of 900 mg of mifepristone with a strong CYP3A inhibitor, after titrating down from 1200 mg of mifepristone:

> **1**. A method of controlling hyperglycemia secondary to hypercortisolism in a patient with endogenous Cushing's syndrome, said patient taking an original once-daily dose of 1200 mg per day of mifepristone, the method comprising the steps of:
>
> reducing the original once-daily dose to an adjusted once-daily dose of 900 milligrams (mg) per day of mifepristone, and
>
> administering the adjusted once-daily dose of 900 mg per day of mifepristone and a strong CYP3A inhibitor to the patient,
>
> wherein said strong CYP3A inhibitor is selected from the group consisting of ketoconazole, itraconazole, nefazodone, ritonavir, nelfinavir, boceprevir, clarithromycin, conivaptan, lopinavir, saquinavir, telaprevir, cobicistat, troleandomycin, tipranivir, and paritaprevir.

[JTX-003.41 ('800 Patent, 67:30–68:2) (Claim 1).]

Independent claim 6 of the '800 Patent is practiced when 900 mg of mifepristone is administered to a patient who is already taking a strong CYP3A inhibitor:

> **6**. A method of controlling hyperglycemia secondary to hypercortisolism in a patient with endogenous Cushing's syndrome, said patient taking a strong CYP3A inhibitor selected from ketoconazole, itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, boceprevir, clarithromycin, conivaptan, lopinavir, posaconazole, saquinavir, telaprevir, cobicistat, troleandomycin, tipranivir, paritaprevir and voriconazole, the method comprising administering to the patient a once-daily dose of mifepristone of 900 milligrams (mg) per day.

[JTX-003.41 ('800 Patent, 68:15–24) (Claim 6).]

F. Teva's ANDA and Generic Mifepristone Product.

Teva filed ANDA No. 211436 with the FDA in December 2017 seeking FDA approval to market, make, use, offer to sell, sell, and/or import a generic version of Korlym® prior to the expiration of the '214 Patent and '800 Patent. [FPTO, Tab 2, Stipulated Facts ¶ 37.] Teva's proposed package insert is identical in all material respects to Corcept's 2019 Korlym® label. [*Compare* JTX-016 (Corcept's 2019 label), *with* JTX-011 (Teva's proposed product label)], and Teva's generic product is

bioequivalent to Korlym®, [FPTO, Tab 2, Stipulated Facts ¶ 41]. On August 2, 2020, the FDA granted Teva's ANDA final approval. [*Id.* ¶ 40.] As of the date hereof, Teva has not yet launched its product.

II. LEGAL STANDARDS

Patent law provides that whoever actively induces infringement "shall be liable as an infringer." 35 U.S.C. § 271(b). To prevail on a theory of induced infringement in the Hatch-Waxman context, a plaintiff must prove two elements: (1) direct infringement, *i.e.*, "if defendant's drug [were] 'put on the market, it would infringe the relevant patent' "; and (2) specific intent, *i.e.*, that the defendant "possessed the specific intent to encourage another's infringement." *Genentech v. Sandoz Inc.*, 55 F.4th 1368, 1376 (Fed. Cir. 2022) (quoting *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1129–30 (Fed. Cir. 2018)).[4]

In a Hatch-Waxman Act case involving a method-of-treatment patent, the "mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). Rather, where it is alleged that the ANDA applicant's proposed label induces physicians to infringe, the label must "encourage, recommend, or promote infringement." *Id.* (citations omitted);

[4] A patent is directly infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent." 35 U.S.C. § 271(a).

see also Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009) ("The question is not . . . whether a user following the instructions may end up using the device in an infringing way. Rather, it is whether [the] instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent."). If the "proposed label instructs users to perform the patented method[,] . . . the proposed label may provide evidence of [the ANDA applicant's] affirmative intent to induce infringement." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010).

The plaintiff, as patentee, bears the burden of proving induced infringement by a preponderance of the evidence. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1366 (Fed. Cir. 2003) (citing *Bristol-Myers Squibb Co. v. Royce Lab'ys, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995)); *SmithKline Diagnostics, Inc. v. Helena Lab'ys Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

III. DISCUSSION

Before proceeding to its analysis, the Court summarizes the parties' arguments. Corcept argues that it has met its burden of establishing Teva's liability for induced infringement under 35 U.S.C. § 271(b). [*See* Pl.'s Post-Trial Br., Docket No. 289.] First, it contends that the expert testimony elicited at trial uniformly demonstrates that Teva's label instructs physicians to perform the patented method when coadministering mifepristone with a strong CYP3A inhibitor. [*Id.* at 2–5.] Corcept next claims that physicians have previously administered mifepristone and a strong

CYP3A inhibitor concomitantly for seriously ill Cushing's syndrome patients and that they are likely to do so in an infringing way in the future. [*Id.* at 5–11.] To this end, it characterizes Dr. Snyder's testimony concerning osilodrostat as a "red herring." [*Id.* at 11–13.]

Second, Corcept argues that Teva's specific intent to induce is clear from Teva's label. Claiming that *HZNP Medicines v. Actavis Laboratories UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019) is distinguishable, Corcept contends that Teva's label does not merely describe infringing activity in an "if/then" manner, but rather instructs physicians to perform the patented method when prescribing Teva's generic mifepristone product. [Pl.'s Post-Trial Br. at 13–17.] It argues that Dr. Synder's opinions regarding encouragement are not credible and that the weight of the evidence supports a finding of intent to induce. [*Id.* at 17–19.] Corcept also submits that Teva's inducement argument does not apply to claim 6 of the '800 Patent because all a physician must do to practice the claim is administer 900 mg of mifepristone to a patient already taking a strong CYP3A inhibitor. [*Id.* at 19–20.] Finally, Corcept asserts that Teva's intent to induce is evidenced by its failure to seek approval of alternative labeling. [*Id.* at 20.]

In opposition, Teva argues that Corcept has failed to meet its burden of demonstrating inducement. [Def.'s Post-Trial Br., Docket No. 288.] Teva contends that there is no record evidence that anyone has ever practiced the patented method, and that the weight of the evidence suggests that coadministration of mifepristone and a strong CYP3A inhibitor in the future is not likely. [*Id.* at 2–9.] In particular, Teva stresses that the introduction of osilodrostat, a recently approved drug that inhibits the

synthesis of cortisol, makes coadministration of mifepristone and strong CYP3A inhibitors obsolete. [*Id.* at 4–5.] Moreover, Teva maintains that its label does not actively induce performance of the patented methods because it discourages the concomitant use of mifepristone with a strong CYP3A inhibitor. [*Id.* at 9–14.] Teva contends that *HZNP* is dispositive of Corcept's inducement argument because Teva's label, like the generic label in *HZNP*, is permissive without encouraging the infringing activity. [*Id.* at 14–17.] Next, it devotes much of the remainder of its submission to distinguishing the cases on which Corcept relies. [*Id.* at 17–20.] In closing, Teva opposes Corcept's "carve-out" argument regarding alternative labeling. [*Id.* at 20.]

The Court discusses each of these arguments, to the extent relevant, below.

A. Direct Infringement.

The asserted claims of the '214 Patent and the '800 Patent are quite similar. Claim 10 of the '214 Patent has the following limitations: (1) it applies to a patient who is taking a once-daily dose of 1200 mg or 900 mg of mifepristone to treat endogenous Cushing's syndrome; (2) the patient's dose is reduced to 600 mg of mifepristone; and (3) the patient is simultaneously administered a strong CYP3A inhibitor. [*See* JTX-001.37.] Claim 1 of the '800 Patent has the following limitations: (1) it applies to a patient who is taking a once-daily dose of 1200 mg of mifepristone to treat endogenous Cushing's syndrome; (2) the patient's dose is reduced to 900 mg of mifepristone; and (3) the patient is simultaneously administered a strong CYP3A inhibitor. [*See* JTX-003.41.] Claim 6 of the '800 Patent has the following limitations:

(1) it applies to a patient who is taking a strong CYP3A inhibitor; and (2) the patient is simultaneously administered a once-daily dose of 900 mg of mifepristone. [*See* JTX-003.41.]

As noted above, to prove direct infringement, Corcept must establish that, if Teva's mifepristone drug product were put on the market, it would infringe the asserted claims of the '214 Patent and the '800 Patent. *See Vanda*, 887 F.3d at 1129–30 (explaining that the inquiry is hypothetical and asks whether the generic drug maker is likely to market an infringing product). A court may consider all relevant evidence in this regard. *See, e.g.*, *Ferring B.V. v. Watson Lab'ys, Inc.-Fla.*, 764 F.3d 1401, 1409 (Fed. Cir. 2014) ("The infringement determination is . . . based on consideration of all the relevant evidence[.]"); *Glaxo*, 110 F.3d at 1570 (noting that district court "properly considered the ANDA itself, the materials submitted by Novopharm to the FDA, and other pertinent evidence" in conducting its infringement analysis). Though "a patentee does not need to prove an actual past instance of direct infringement" to establish liability for inducement, *Vanda*, 887 F.3d at 1129, 1129–30, "past conduct is relevant to what will happen in the future," *Genentech*, 55 F.4th at 1379, 1379–80.

1. Evidence of Prior Infringement.

The Court begins with the lack of record evidence demonstrating that anyone has ever practiced the claimed methods, including during the ten-year span since Korlym® was approved. Teva contends that *Genentech* "dismantles Corcept's infringement case" for this reason. [Def.'s Post-Trial Br. at 8–9; *see also* Def.'s Pre-

Trial Br. 9–10.] Corcept asserts that Teva's reliance on *Genentech* is misplaced because it did not "change[] the law" to "***require***" the Court to consider past conduct in determining whether infringement will likely occur in the future. [Pl.'s Post-Trial Br. at 5–6; *see also* Pl.'s Pre-Trial Br. 27–30.] The *Genentech* court looked outside of the generic manufacturer's proposed product label to prior physician conduct only because it found that the label did not recommend practice of the claimed methods, Corcept argues. [Pl.'s Post-Trial Br. at 5; *see also* Pl.'s Post-Trial Reply Br. at 4.]

In *Genentech*, the Federal Circuit considered certain patented methods for avoiding adverse drug interactions between pirfenidone, a medication to treat idiopathic pulmonary fibrosis, and fluvoxamine, a strong CYP1A2 inhibitor. 55 F.4th at 1371, 1374. The drug-drug interaction patents at issue involved administering pirfenidone to a patient already taking fluvoxamine by either discontinuing fluvoxamine or titrating the pirfenidone dose and continuing fluvoxamine. *Id.* at 1374–75. The generic manufacturer's proposed label warned about the drug-drug interactions, specifically stating that "concomitant administration" is "***not recommended***" and "[u]se of fluvoxamine . . . should be discontinued prior to administration of pirfenidone and avoided during pirfenidone treatment." *Id.* at 1375 (emphasis added). Still, the label permitted coadministration of the two agents when necessary and provided dosing instructions in such case. *See id.* ("In the event that fluvoxamine or other strong CYP1A2 inhibitors are the only drug of choice, dosage reductions are recommended. Monitor for adverse reactions and consider

discontinuation of pirfenidone as needed *[see Dosage and Administration (2.4)]*.") (brackets and emphasis in original).

The district court determined that the patentee had not met its burden of establishing direct infringement, and the Federal Circuit affirmed for two principal reasons. *Id.* First, there was no record evidence that any physicians had ever practiced the patented methods, and "past conduct is relevant to what will happen in the future." *Id.* at 1379. Second, the generic manufacturer had presented evidence from physicians who testified that "they had never prescribed pirfenidone to an [idiopathic pulmonary fibrosis] patient taking fluvoxamine" and that they would prescribe a noninfringing alternative (*i.e.*, nintedanib) if placed in that situation. *Id.* at 1380. "The court did not clearly err by considering all relevant evidence, including Sandoz's proposed label and physician practice." *Id.*

Here, Corcept's attempt to discredit *Genentech* is unavailing. Teva is not claiming that a "split-panel decision" changed the law, as Corcept says [*see* Pl.'s Post-Trial Br. at 5], nor that this Court ***must*** credit the lack of evidence of past infringement. Rather, Teva correctly contends that such evidence is relevant. There is nothing new about the proposition for which the case is cited. *See, e.g.*, *Takeda*, 785 F.3d at 634 (affirming district court finding of no inducement based on insufficient evidence that healthcare provider had actually practiced claimed methods and patentee had not otherwise met threshold element of direct infringement) (citing *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1341 (Fed. Cir. 2008)); *accord Limelight Networks, Inc. v.*

Akamai Techs. Inc., 572 U.S. 915, 921–22 (2014) (explaining that inducement liability can arise "if, but only if, there is direct infringement") (citation omitted) (cleaned up). Moreover, the Federal Circuit in *Genentech* did not hold that evidence of physician practice is only relevant if the product label fails to recommend an infringing use. Corcept's reading of *Genentech* would collapse the distinct elements of induced infringement into one inquiry focused exclusively on the language of the product label. That is not the law. As the trial court explained,

> The presence of language that "encourages, recommends or promotes" an infringing use on a proposed label, without any additional evidence showing such an infringing use will in fact occur, especially where there is evidence that an infringing use likely will not occur, is insufficient for a finding of induced infringement.

Genentech, Inc. v. Sandoz, Inc., 592 F. Supp. 3d 355, 376 (D. Del.), *aff'd*, 55 F.4th 1368 (Fed. Cir. 2022).[5]

Just as the *Genentech* courts concluded, and mindful of Corcept's burden, this Court finds the lack of record evidence that any physician has ever practiced the asserted claims to be persuasive—here, as a starting point to its analysis. Neither Dr. Carroll (Corcept's expert) nor Dr. Snyder (Teva's expert) has ever prescribed mifepristone with a strong CYP3A inhibitor to treat Cushing's syndrome. [Tr. at 266:9–12, 266:18–23, 270:3–9, 273:17–19 (Dr. Carroll); Tr. at 410:9–22 (Dr. Snyder).] Though Dr. Carroll testified regarding other physicians' occasional coadministration

[5] The trial court did not reach the question whether the patentee had demonstrated specific intent to induce infringement because it concluded that the patentee had failed to prove direct infringement.

of mifepristone with strong CYP3A inhibitors to treat especially ill patients, [*see, e.g.*, Tr. at 236:22–238:2 (referencing Dr. Hamrahian)], it is critical to note that Dr. Carroll did not provide evidence that any physician had ever prescribed the drugs together at an infringing sequence and/or dosage, [*see* Tr. at 270:20–23, 285:2–19.] Dr. Snyder also did not identify any instances of past practice of the asserted claims. [Tr. at 392:22–393:5.] The parties' experts thus did not testify regarding prior direct infringement.

Similarly, the other Corcept (as well as Teva) witnesses did not provide testimony that they had ever practiced Corcept's patented methods. Dr. Dobbs, for instance, indicated that she had combined ketoconazole with mifepristone "two to three times" in her career to take advantage of their "different mechanisms of action" for "extremely ill" patients, [Tr. at 58:16–25], but she did not provide testimony concerning the dosage or sequence employed. The other witnesses are no different. [*See, e.g.*, Tr. at 96:18–23, 97:23–98:15 (Dr. Moraitis indicating that he has never treated a Cushing's syndrome patient with a combination of mifepristone and ketoconazole and is not aware of any who have).] While the record undisputedly reveals that physicians have coadministered mifepristone with a strong CYP3A inhibitor in rare cases, [*see, e.g.*, Tr. at 244:25–245:14 (Dr. Carroll crediting case report of patient who both ketoconazole and mifepristone for treatment of Cushing's syndrome)], Corcept did not present the Court with any specific evidence where a physician practiced the patented methods. This is notwithstanding the fact that Korlym® has been commercially available since April 2012. The absence of this

relevant information leads to the conclusion that future direct infringement is not likely.[6] *See Genentech*, 55 F.4th at 1379–80; *Takeda*, 785 F.3d at 634.

2. Evidence of Future Infringement.

Next, the Court addresses whether Corcept has met its burden of proof that it is more likely than not that direct infringement of the asserted claims will occur in the future based on other record evidence. Crediting Dr. Snyder's testimony, this Court

[6] On November 2, 2023, the Court observed in a Letter Order that Corcept had not pointed to record evidence of prior instances of coadministration at an infringing sequence or dosage. [Docket No. 292, at 2.] While not required, the Court emphasized that "the existence—or absence—of such prior infringement evidence" was important to its analysis. [*Id.*] The Court reminded Corcept that it had invited this evidence during and after trial. [*Id.*] In its Post-Trial Reply Brief, Corcept interpreted the Court's letter as an opportunity to reopen the trial record to include a set of belated declarations from medical professionals attesting, in summary fashion, that each has practiced one or more of the claimed methods in the past. [Pl.'s Post-Trial Reply Br. at 5 & Exs. A–F, Docket No. 295.] This is not what the Court invited, nor will the Court grant Corcept's request at this stage. Courts have considerable discretion in deciding whether to reopen the trial record to permit additional evidence. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 331 (1971). In making this decision, courts consider several factors, including (1) the burden on the parties and their witnesses, (2) any undue prejudice that may result to the nonmoving party, and (3) the impact on judicial economy. *See Rochez Bros., Inc. v. Rhoades*, 527 F.2d 891, 894 n.6 (3d Cir. 1975). The trial record may be reopened when the failure to adduce sufficient evidence is based on a reasonable misunderstanding or when it is to ensure substantial justice. *See id.* at 894–95. Here, Corcept has had ample opportunity during this litigation to introduce specific evidence that physicians have practiced the patented methods. Indeed, courts routinely consider this evidence when assessing whether a patentee has made a threshold showing that future direct infringement is likely. *See, e.g.*, *Takeda*, 785 F.3d at 634. It would be too prejudicial now to consider Corcept's hearsay declarations over Teva's objection, and it would be inappropriate and burdensome to delay resolution of this matter to further examine this issue. Corcept has not persuaded the Court that its lack of prior infringement evidence stems from a reasonable misunderstanding, or that reopening the trial record is necessary to ensure substantial justice. Therefore, Corcept's request must be denied.

finds that, while clinicians may exercise their medical judgment to coadminister mifepristone with a strong CYP3A inhibitor in isolated instances "when necessary," it is highly unlikely that physicians will practice the claimed methods.

First, the record evidence demonstrates that physicians generally avoid coadministering mifepristone and strong CYP3A inhibitors. They avoid doing so because of the challenges of dosing mifepristone and the dangers associated with coadministering the two substances.

The evidence established that mifepristone does not inhibit the production of cortisol, but rather blocks its effects. [Tr. at 121:5–6 (Dr. Belanoff); Tr. at 383:9–12 (Dr. Snyder).] As a result, mifepristone can cause a patient's cortisol blood concentrations to increase. [Tr. at 384:24–385:5 (Dr. Snyder).] Physicians thus cannot rely on circulating blood levels of ACTH and/or cortisol to reflect therapeutic efficacy of mifepristone when treating Cushing's syndrome patients. [*See* Tr. at 158:25–163:20 (Dr. Belanoff); *see also* James W. Chu *et al.*, *Successful Long-Term Treatment of Refractory Cushing's Disease with High-Dose Mifepristone (RU 486)*, 86 J. Clinical Endocrinology & Metabolism 3568, 3570, 3572 (2001) (explaining that difficulty in monitoring therapeutic efficacy of mifepristone stems from lack of objective measure of receptor activity) [DTX-043.0004].] This is mifepristone's principal disadvantage in this context. [*See* Tr. at 385:16–20 (Dr. Snyder) ("[T]he major drawback is that because it doesn't block the production of cortisol, one cannot use cortisol to determine if one is giving the right dose. So one doesn't know if one's giving the right dose or too much or too little.").]

Strong CYP3A inhibitors, such as ketoconazole, impede the synthesis of cortisol in the adrenal glands, thereby "blocking" excessive cortisol at its source. [Tr. at 383:6–12 (Dr. Snyder).] Because these medications suppress the activity of CYP3A enzymes, they can raise mifepristone blood concentrations and increase the chances of severe side effects when taken together. [Tr. at 127:19–24 (Dr. Belanoff); Tr. at 303:9–22 (Dr. Carroll); Tr. at 395:5–8 (Dr. Snyder).] Partly on this basis, Dr. Moraitis reported that he strongly prefers monotherapy because of the possibility of adverse drug-drug interactions. [*Cf.* Tr. at 96–97 (explaining that he avoids combining agents because combination usually fails and requires more aggressive intervention).]

Given this context, and opining on Teva's label, Dr. Snyder persuasively testified that physicians should "be very afraid" of coadministration, that it could cause a "problem." [*See* Tr. at 394:11, 397:22.] He explained that he would not likely use mifepristone today to treat Cushing's syndrome because of the dosing problem outlined above. [Tr. at 386:9–11.] And the problem is not without consequence: too little mifepristone, and the patient continues to have Cushing's syndrome, with all its attending consequences; too much mifepristone, and the patient's blood pressure could drop, even causing death. [Tr. at 385:21–25, 386:1–8 (Dr. Snyder).] "I am not aware of any authority in the area of Cushing's syndrome who *recommends* combining mifepristone with another medication." [Tr. at 413:10–12 (Dr. Snyder) (emphasis added).] The Court finds Dr. Snyder's testimony credible. It is significant that Dr. Lynette Nieman, a leading authority on the treatment of Cushing's syndrome, did not mention combining mifepristone with other drugs in a topic review of hers published

in UpToDate®, a medical periodical for which Dr. Snyder serves a co-editor-in-chief. [*See* Tr. at 413:21–418:20 (discussing Lynette K. Nieman, *Medical Therapy of Hypercortisolism (Cushing's Syndrome)*, UpToDate (last updated Aug. 29, 2022) [DTX-034]).[7]] Dr. Snyder suggests that the absence of any such discussion in sections of the topic review addressing combination therapy is telling, [*see* Tr. at 418:7–10], and this Court agrees. Indeed, Corcept had no real response.

Second, and relatedly, the existence of at least one non-infringing alternative treatment to mifepristone suggests that physicians are not likely to directly infringe the asserted claims in the future. As Dr. Snyder testified, the recent introduction of osilodrostat has "changed" the "landscape." [Tr. at 386:13–17.] Osilodrostat is a "powerful" and "effective" drug that "acts rapidly." [Tr. at 386:19–22.] Unlike mifepristone, osilodrostat blocks cortisol production, so physicians can use cortisol blood concentrations to determine effective dosage. [Tr. at 384:9–12, 386:17–22, 484:10–20.] Dr. Snyder opined that physicians are unlikely to coadminister mifepristone and strong CYP3A inhibitors in the future because osilodrostat is a better drug to treat Cushing's syndrome. [Tr. at 393:11–18; *see also* Tr. at 489:22–24 ("So it is safer to give osilodrostat than to give mifepristone, in spite of the fact that the blood

[7] Still, the Court notes that the article refers to the danger of combining ketoconazole with CYP3A4 substrates: "Ketoconazole is a strong inhibitor of CYP3A4. Coadministration of CYP3A4 substrates should be avoided if possible and may result in increased plasma concentrations of these drugs, with increased or prolonged therapeutic or adverse effects." Nieman, *supra*, at 4 (Initial Therapy – Ketoconazole) [DTX-034.0004].

concentration has changed more with osilodrostat."] This is so even though, as Corcept elicited on cross-examination, osilodrostat is only indicated for the treatment of Cushing's disease. [*See* Tr. at 474:2–15 (Dr. Snyder) (explaining that Isturisa®, or osilodrostat, while only FDA-approved for treatment of Cushing's disease, is widely used off-label for Cushing's syndrome); Tr. at 476:21–25 (Dr. Snyder) ("[I]t is, I'd say, even desirable to use osilodrostat for any form of Cushing's syndrome, and preferable to use it compared to mifepristone. I think it's medically preferrable.").] In summary, Dr. Snyder concluded that in his personal experience, the benefits of coadministering mifepristone and ketoconazole never outweigh the risks, especially since the introduction of osilodrostat. [Tr. at 410:9–14.] The Court finds this testimony credible and persuasive.

Corcept's arguments are not to the contrary. For instance, Corcept argues that Teva presented no evidence that "even a single prescription" of Korlym® has been lost to osilodrostat. [Pl.'s Post-Trial Br. at 11, 11–12.] Corcept points to Dr. Belanoff's testimony that since the FDA approved Isturisa® (osilodrostat) in 2020, Corcept has actually experienced increased sales. [*See* Tr. at 123:23–124:3.] He attributes the increase in sales to heightened visibility of hypercortisolism treatments and better screening by physicians. [Tr. at 124:7–125:1.] In other words, Dr. Belanoff claims that the introduction of a competing drug, with a different mechanism of action, has had a positive impact for the company. [*See* Tr. at 124:21–125:1.] While the Court has no reason to disbelieve that greater awareness about hypercortisolism has certain salubrious effects, Dr. Belanoff's explanation about increased sales was by no means

a causal analysis. And Corcept failed to prove that the increase is ***because of*** the introduction of osilodrostat. Dr. Belanoff's testimony left more questions in the Court's mind than answers. [*See* Tr. at 412:20–21 (Dr. Synder stating that he was "puzzled" by the suggestion that osilodrostat has increased Corcept's sales of Korlym®).] Therefore, based on the evidence elicited at trial, the Court cannot conclude that osilodrostat will ***not*** be preferred to Korlym® in the future, as Dr. Snyder persuasively testified.

Third, Corcept has not met its burden of demonstrating that direct infringement is likely to occur even if a physician consults Teva's proposed label to coadminister mifepristone and a strong CYP3A inhibitor. As will be discussed further below, Teva's label does not induce physicians to administer the drugs together. Rather, the label cautions against coadministration, providing dosing instructions if a physician independently determines that it is medically necessary to prescribe mifepristone and a strong CYP3A inhibitor together. Corcept has maintained that physicians will infringe the asserted claims by following Teva's label because the label's instructions are not "optional." [Pl.'s Post-Trial Br. at 9–11, 13–17.] But this position ignores that a physician could follow the instructions on Teva's label and not infringe the claims. As Corcept's own expert, Dr. Carroll, acknowledged, administering 300 mg of mifepristone to a patient who is already taking a strong CYP3A inhibitor ***would not infringe*** claim 6 of the '800 Patent. [Tr. at 267:5–9, 268:5–12.] ***Nor would administering 600 mg of mifepristone***. A physician infringes claim 6 only by administering 900 mg of

mifepristone to a patient who is already taking a strong CYP3A inhibitor. [JTX-003.41.]

Similarly, a physician who administers a strong CYP3A inhibitor to a patient who is already taking 300 mg or 600 mg of mifepristone ***would not infringe*** claim 10 of the '214 Patent or claim 1 of the '800 Patent. [*See* Tr. at 261:14–264:8 (Dr. Carroll) (acknowledging that these scenarios, and others, fall outside the claimed methods).] Claim 10 is only practiced when a Cushing's patient is already taking 1200 mg or 900 mg of mifepristone, and the physician lowers the patient's dose to 600 mg of mifepristone and administers a strong CYP3A inhibitor. [JTX-001.37.] Claim 1 is only practiced when a Cushing's patient is already taking 1200 mg of mifepristone, and the physician lowers the patient's dose to 900 mg and administers a strong CYP3A inhibitor. [JTX-003.41.]

Corcept largely ignores these non-infringing possibilities. Instead, it contends that infringement will occur because most patients require 900 mg or 1200 mg of mifepristone to achieve an efficacious result. [Pl.'s Post-Trial Br. at 9–10.] The Court does not find this argument to be compelling. First, the testimony elicited on this score from Dr. Belanoff and Dr. Carroll focused on the optimal dose reported in the SEISMIC study that supported the FDA's initial approval of Korlym® in 2012. [*See* Tr. at 147:4–6 (Dr. Belanoff); Tr. at 320:23–321:2 (Dr. Carroll).] Only 34 patients participated in this study. [Tr. at 333:6–9 (Dr. Carroll).] Despite years of discovery, Corcept did not introduce any evidence regarding the average dose of Korlym® that patients receive in practice, or the number of patients who have taken 300 mg, 600 mg,

900 mg, or 1200 mg of Korlym®, or the number of patients who have taken Korlym® together with ketoconazole. The logical conclusion is that Corcept does not know this information. [*See* Tr. at 83:19–21, 81:19–82:3, 82:10–14 (Mr. Maduck, Corcept's Chief Commercial Officer).] As a result, Corcept has not persuaded this Court that today most patients who receive a strong CYP3A inhibitor are already taking at least 900 mg of Korlym® or that patients who are already receiving a strong CYP3A inhibitor will be prescribed at least 900 mg of Korlym®. Therefore, the Court concludes that physicians are not likely to titrate Cushing's syndrome patients' dosage of mifepristone in an infringing manner. Accordingly, Corcept has not demonstrated that physicians, following Teva's label, would necessarily infringe the asserted claims.

Corcept's other arguments fail to persuade the Court that direct infringement is likely. For instance, Corcept contends that physicians will infringe the asserted claims because ketoconazole remains the most commonly used medication to treat manifestations of Cushing's syndrome. [Pl.'s Post-Trial Br. at 7.] Corcept also argues that patients taking mifepristone may require ketoconazole if they develop an opportunistic infection, such as aspergillosis. [*Id*. at 8.] Even crediting the testimony on which Corcept's argument is based, [*see, e.g.*, Tr. at 229:18–234:16 (Dr. Carroll) (opining that it might be "medically necessary" to coadminister mifepristone with a strong CYP3A inhibitor where certain infections occur in a patient with Cushing's syndrome) (first citing J.K. Oosterhuis *et al.*, *Life-Threatening* Pneumocystis Jiroveci *Pneumonia Following Treatment of Severe Cushing's Syndrome*, 65 Netherlands J. Med. 215 (2007) [PTX-016]); then citing Pivonello *et al.*, *supra*), the Court does not find that

infringement will likely result. As the Court has already explained, Dr. Carroll's testimony is not supported by any credible instances in which a physician practiced the claimed method, and a physician can faithfully follow Teva's label and avoid infringement. Given these reasons, and Dr. Snyder's testimony, the Court must reject Corcept's conclusion that infringement will occur.

Therefore, for the above reasons, the Court finds that Corcept has not met its burden of demonstrating that direct infringement of the '214 Patent and the '800 Patent is likely. *See Takeda*, 785 F.3d at 635 (finding that court permissibly concluded direct infringement was unlikely based on testimony from physicians that they try to avoid coadministration of drugs and lack of evidence that claimed method would actually be practiced).

B. Specific Intent.

Next, the Court addresses whether Teva's label "instructs users to perform the patented method." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). To answer the question, the Court asks whether the label "encourage[s], recommend[s], or promote[s] infringement." *Takeda*, 785 F.3d at 631. "[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce must be proven." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (citation omitted). The Court reaches this question for the sake of completeness, even though it has concluded that Corcept has not shown a likelihood that Teva's generic product would directly infringe the asserted claims if

marketed. *See Limelight Networks*, 572 U.S. at 921–22 (explaining that likelihood of direct infringement is a threshold requirement for inducement liability).

Corcept contends that Teva's intent to induce infringement can be inferred from Teva's product label. [*See* Pl.'s Post-Trial Br. at 13–17.] Corcept maintains that the label instructs physicians to follow dosage adjustment steps that infringe the asserted claims, and it submits that the appropriate test is not whether the label recommends coadministration, but whether the label recommends that physicians follow the claimed method once it has been decided to administer the drugs together. [*Id.*] Relying on *HZNP*, 940 F.3d at 702, Teva counters that "an instruction *how* to do something is not an instruction *whether* to do it in the first place." [Def.'s Post-Trial Br. at 10, 14–17.]

In *HZNP*, the Federal Circuit considered whether Horizon had met its burden of showing that Actavis's product label induced a use of Actavis's proposed product that would infringe Horizon's method-of-use patents. 940 F.3d at 699. The product at issue was a topical solution for the treatment of osteoarthritis pain of the knees, and Horizon's patents addressed its method of application. *Id.* As the court summarized, the patented method required three steps: (1) applying the topical solution; (2) waiting for the area to dry; and (3) applying sunscreen, insect repellant, or a second topical medication. *Id.* at 702. Actavis's proposed label, materially identical to Horizon's label for its branded product, recommended a specified dosage of the solution and instructed users to apply the solution to the clean, dry skin of the knee twice a day. *Id.* at 699. It also warned that users should wait until the treated area was completely dry

before covering with clothing, applying sunscreen, insect repellent, or other substances. *Id.* at 699–700.

Horizon argued that Actavis's label reflected its specific intent to induce infringement because it tracked, nearly exactly, Horizon's three-step, patented method of applying the topical solution. *Id.* at 701. Horizon contended that if a user sought to apply sunscreen, insect repellant, or another substance, then direct infringement would occur, as the user would follow the patented method and wait until the user's skin was dry before applying the other substance to the treated area. *Id.*

The Federal Circuit rejected Horizon's argument. It explained that Actavis's label, properly construed, only *required* step one, *i.e.*, application of the topical solution. *Id.* at 702. Post-product application of sunscreen or another substance was not required by the label. Rather, the label's warning operated in an " 'if/then' manner: *if* the user wants to cover the treated area with clothing or apply another substance over it, then the patient should wait until the area is dry." *Id.* This construction, the Federal Circuit explained, does not "encourage, recommend, or promote" infringement; the label "merely provided guidance to patients about what to do if the pat[i]ent desired to have anything come into contact with the knee after application of the medication." *Id.* While a user may infringe Horizon's method-of-use patents, the court reaffirmed that evidence of direct infringement is not sufficient to establish that a proposed label instructs the user to perform the patented method. *Id.*

HZNP is instructive here. Just as the product label in *HZNP* did not encourage, promote, or recommend the specified steps of the patented method because nothing

required post-product application of sunscreen or another substance, 940 F.3d at 702, Teva's label does not encourage physicians to practice the asserted claims because the label does not encourage coadministration of mifepristone and a strong CYP3A inhibitor. The label only provides instructions *how* to coadminister the substances to achieve an efficacious result *if* a physician determines that it is medically necessary. In this context, the label only provides "guidance" for physicians; it does not teach an infringing use "such that we are willing to infer from those instructions an affirmative intent to infringe the patent." *Vita-Mix*, 581 F.3d at 1329 n.2.

The Court thus rejects Corcept's attempts to distinguish *HZNP*. For instance, Corcept argued that a recent decision by another court in this District demonstrates why *HZNP* is distinguishable. [*See* Pl.'s Post-Trial Br. at 16–17 (discussing *Janssen Pharms., Inc. v. Mylan Labs. Ltd.*, 2023 WL 3605733 (D.N.J. May 23, 2023) (Padin, J.).] In *Janssen*, the court confronted a patented method for reinitiating treatment of schizophrenia in patients who had missed their last dose of a three-month paliperidone palmitate extended-release injectable medication within a four-to-nine-month window. 2023 WL 3605733, *5–7. The patent specifications described a "reinitiation dosing regimen." *Id.* at *7. The generic label at issue instructed clinicians to apply the regimen in the "inevitable" situation that a patient returns between four and nine months after a missed dose. *Id.* at *15–16. Rejecting the generic manufacturer's argument that its label did not induce infringement because a warning discouraged missing a dose, the court explained that the label does not "discourage or make optional the practice of the Asserted Claims (or any claimed steps) in the inevitable

situation that doses ***are*** missed." *Id.* at *17. The *Janssen* court also suggested that *HZNP* supported its finding of induced infringement because there "one of the claimed steps was optional." *Id.* (citing *HZNP*, 940 F.3d at 702).

Here, Corcept has failed to demonstrate that a similarly "inevitable" situation is present. Unlike the missed doses in *Janssen* that were likely to occur based on the credible record evidence that more than 50 percent of patients miss a dose, *see Janssen*, 2023 WL 3605733, at *15, there is no external trigger here that is likely to convince a physician to coadminister mifepristone and a strong CYP3A inhibitor. The record evidence reveals that physicians are unlikely to coadminister the two substances, and even less likely to do so in an infringing manner. Furthermore, contrary to *Janssen*, a physician here can faithfully follow Teva's label and not infringe the asserted claims. There are non-infringing options available. Therefore, Corcept's efforts to differentiate *HZNP* are unconvincing.

Two additional points bear emphasizing. First, Teva's label does not affirmatively encourage the coadministration of mifepristone with a strong CYP3A inhibitor. The label does not outline any benefits of coadministration or indicate the circumstances in which the agents should be coadministered. [Tr. at 399:16–22 (Dr. Snyder).] Rather, Teva's label warns physicians *against* coadministration, advising the exercise of caution if they choose to do so.[8] [*See, e.g.*, JTX-011.1 (**WARNINGS AND**

[8] Dr. Belanoff acknowledged that Corcept's 2012 label represented a "forceful[]" warning against coadministration, that physicians were taught to avoid the use of mifepristone with a strong CYP3A inhibitor. [JTX-005.682 (Dr. Belanoff Decl. to

PRECAUTIONS – "*Use of Strong CYP3A Inhibitors*: Concomitant use can increase mifepristone plasma levels. Use only when necessary and limit mifepristone dose to 900 mg (5.6)."); JTX-011.1 (**DRUG INTERACTIONS** – "CYP3A inhibitors: Caution should be used when mifepristone is used with strong CYP3A inhibitors."), JTX-011.4, § 2.5 & Tbl. 1 ("Mifepristone tablets should be used in combination with strong CYP3A inhibitors only when necessary."); JTX-011.5–6, § 5.6 ("The benefit of concomitant use of these agents should be carefully weighed against the potential risks."); JTX-011.9, § 7.2 ("Caution should be used when strong CYP3A inhibitors are prescribed in combination with mifepristone. The benefit of concomitant use of these agents should be carefully weighed against the potential risks.").] Dr. Snyder credibly testified that physicians would read Teva's label as a warning not to coadminister mifepristone and a strong CYP3A inhibitor, unless medically necessary (*i.e.*, unless the

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Patent Office); Tr. at 169:24–170:12, 171:12–15 (Dr. Belanoff).] After additional study of mifepristone, Corcept discovered that coadministration did not raise the blood concentration of mifepristone as much as was previously believed. Accordingly, Corcept's label was revised in degree: the 2019 label recommended "caution" instead of "extreme caution" and indicated that the allowable dose of mifepristone was 900 mg instead of 300 mg of mifepristone, among other relevant changes. [*Compare* JTX-016.6, *with* JTX-015.6.] Though there are meaningful differences between the 2012 label and 2019 label based on this breakthrough, the current label still represents a warning against coadministration. Therefore, the label's history reinforces the Court's conclusion that Teva's label, like Corcept's 2019 label, does not encourage the coadministration of mifepristone and strong CYP3A inhibitors. *See United Therapeutics Corp. v. Sandoz, Inc.*, 2014 WL 4259153, at *18 (D.N.J. Aug. 29, 2014) ("[T]here is a rather significant difference between a warning and an instruction. A warning provides information regarding a potential risk. It does not prescribe a course of action.").

benefit to the patient outweighs the risks). [*See* Tr. at 393:11–18, 394:18–395:8, 396:14–18, 397:7–22, 399:4–12.]

Second, in the unlikely event that a physician decides to coadminister mifepristone with a strong CYP3A inhibitor, Teva's label does not provide exclusively infringing instructions. Said differently, Teva's label permits non-infringing options for coadministering the substances. Infringement thus cannot be assumed. *See Warner-Lambert Co.*, 316 F.3d at 1364–65 ("[T]he request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe."). For instance, as Corcept's own expert acknowledged, a physician could prescribe up to 600 mg of mifepristone to a patient who is already taking a strong CYP3A inhibitor and not infringe any of the asserted claims. [*See* Tr. at 268:5–270:9 (Dr. Carroll) (describing the series of steps required over the course of months for a physician to infringe claim 6 of the '800 Patent); *see also* JTX-001.37 ('214 Patent, claim 10); JTX-003.41 ('800 Patent, claim 1); JTX-003.41 ('800 Patent, claim 6).] Similarly, prescribing a strong CYP3A inhibitor and 300 mg or 600 mg of mifepristone to a patient would not infringe the asserted claims either. [*See* Tr. at 271:18–272:17 (Dr. Carroll) (acknowledging that § 2.5 of Teva's label would not result in infringement if strong CYP3A inhibitor added where patient already taking 300 mg or 600 mg of mifepristone); *see also* JTX-001.37 ('214 Patent, claim 10); JTX-003.41 ('800 Patent, claim 1); JTX-003.41 ('800 Patent, claim 6).] *See also supra* Section III.A.2 (pp. 35–36).

Accordingly, because Teva's label cautions physicians against coadministering mifepristone with a strong CYP3A inhibitor unless medically necessary and because infringement of Corcept's patented method is not guaranteed if a physician decides to coadminister the substances, the Court will not infer Teva's specific intent to induce infringement of the asserted claims. *See HZNP*, 940 F.3d at 702; *Vita-Mix*, 581 F.3d at 1329 n.2; *Takeda*, 785 F.3d at 631, 634–35.

Finally, Corcept's remaining arguments fail to persuade the Court to adopt a contrary conclusion. For example, Corcept submits that Teva's intent to induce is evidenced by its failure to seek alternative labeling given its position that coadministration is dangerous. "[H]ad Teva actually believed this, it could have petitioned the FDA to allow Teva to revert back to the original, more restrictive, 2012 Korlym label." [Pl.'s Post-Trial Br. at 20.] It cites this Court's disposition of *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 615, 618 (D.N.J. 2009) (Bumb, J.). Corcept's argument is unconvincing. In *AstraZeneca*, Apotex's attempt to develop an alternative, non-infringing label was at the heart of the Court's analysis of specific intent, in part because the evidence suggested Apotex was aware of an infringement problem and persisted in distributing its generic drug nevertheless. *See id.* at 616, 618; *see also AstraZeneca*, 633 F.3d at 1060–61.

Here, as the Court previously explained, no such infringement problem exists, and Corcept has not met its burden of demonstrating a likelihood of direct infringement if Teva's mifepristone were placed on the market. Furthermore, evidence that a label was materially altered can demonstrate a defendant's lack of intent to

induce infringement. *See, e.g.*, *United Therapeutics*, 2014 WL 4259153, at *17–21 (rejecting a patentee's argument that carve out should be discounted because information remaining in generic product's label amounted to an "implicit" instruction). But the reverse is not true. The Court is not aware of any precedent requiring an ANDA applicant to modify its product label to avoid direct infringement arguments. That would turn the legal test "on its head." *See Takeda*, 785 F.3d at 632 n.4 (explaining that patentee needs to show that ANDA applicant took affirmative steps to induce, "not affirmative steps to make sure others avoid infringement").

IV. CONCLUSION

In sum, the Court concludes that Corcept has not met its burden of proving induced infringement pursuant to 35 U.S.C. § 271(b). Corcept has not demonstrated that direct infringement of the asserted claims is more likely than not if Teva's generic mifepristone product were placed on the market, and Corcept has not persuaded the Court of Teva's affirmative intent to induce infringement based on the language contained in Teva's product label. Because the credible record evidence discloses that no one has ever practiced the patented method, that physicians seek to avoid coadministering mifepristone and strong CYP3A inhibitors, that non-infringing alternatives are available, and that Teva's product label discourages physicians from coadministering, among other reasons, the Court will enter judgment in Teva's favor. An accompanying Order shall issue separately. Fed. R. Civ. P. 58(a).

s/Renée Marie Bumb
RENÉE MARIE BUMB
Chief United States District Judge

DATED: **December 29, 2023**